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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/549,463 04/14/00 HAITEBOER G 4038.1US

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HM12/1002

EXAMINER

MITRA, R

ART UNIT	PAPER NUMBER
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1653

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/549,463

Applicant(s)

HATTEBOER ET AL.

Examiner

Rita Mitra

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2000.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-9, 11, 13, 14, 18-34, 37-41, 43, 45, 47, 49, 51-54, 57, 58, 63, 64, 69-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 1-9,11,13,14,18-34,37-41,43,45,47,49,51-54,57,58,63,64 and 69-72.

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 5-7, 11, 13 14 and 22 are drawn to a method for producing a proteinaceous substance in a eukaryotic cell comprising providing a cell having nucleic acid sequence encoding adenoviral E1A protein, providing said cell with a gene encoding proteinaceous substance, a recombinant mammalian cell; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- II. Claims 2, 4 are drawn to a method for enhancing producing a proteinaceous substance in a eukaryotic cell comprising providing a cell with a gene, wherein nucleic acid is under control of a CMV promoter, an E1A promoter; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- III. Claims 8, 9 and 69 are drawn to a method for producing a proteinaceous substance in a eukaryotic cell comprising providing a cell having nucleic acid sequence encoding adenoviral E1B protein, providing said cell with a gene encoding proteinaceous substance, a recombinant mammalian cell; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

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- IV. Claims 33, 34, 18, 19, 21, 23-25, 28-32, and 72 are drawn to a method for producing a variable domain of an immunoglobulin, a recombinant mammalian cell; classified in Class 435, subclasses 69.1, 455, 252.3, and 320.1, class 530, subclass 387.1
- V. Claims 37, 38 are drawn to a variable domain of an immunoglobulin produced by the method of claim 33; classified in 530, subclass 350.
- VI. Claims 39, 40, 41, 43, 45, 47, 49, 51, 52 and 53 are drawn to a method for producing a viral protein in a eukaryotic cell comprising providing a cell having nucleic acid sequence encoding adenoviral E1A protein, providing said cell with a gene encoding viral protein; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
Should Group V be elected, applicants are required to select one virus for the selection of viral protein.
- VII. Claims 54, 70 and 71 are drawn to a method for producing a vaccine comprising a viral protein in a human cell, having a sequence encoding adenoviral E1A protein; classified in Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- VIII. Claims 57, 58, 26, 27 are drawn to a method for producing a proteinaceous substance in a eukaryotic cell comprising providing a cell having nucleic acid sequence encoding adenoviral E1A protein, further comprising E2A protein, a recombinant mammalian cell; classified in Class 536, subclass 23.1; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- IX. Claims 63, 64, drawn to a recombinant erythropoietin molecule produced by the method of claims 1, 2 or 6; classified in Class 530, subclasses 350.

The inventions are distinct, each from the other because of the following reasons:

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Groups I, II, III, VI are different methods. Methods of making products and methods of enhancing the production differ with respect to ingredients, method steps, and endpoints; method of I, II, III and VII differ by ingredients E1A, CMV promoter, E1B and viral protein respectively. Therefore, each method is patentably distinct.

Groups I, II, III, VI, and IV, VII are different methods. Methods of making products and methods of enhancing the production differ with respect to ingredients, method steps, and endpoints; method of I, II, III, VI differ by endpoints variable domain of IV and vaccine of VII. Therefore, each method is patentably distinct.

Groups I, II, III, VI, and IV, VII, VIII are different methods. Methods of making products and methods of enhancing the production differ with respect to ingredients, method steps, and endpoints; methods of IV, VII and VIII differ by additional adenoviral E2A. Therefore, each method is patentably distinct.

Groups I, II and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

Groups IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

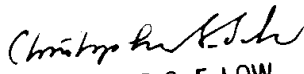
Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.
September 30, 2001



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